UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTIONS IN LIMINE

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Plaintiffs Federal Trade Commission and the People of the State of New York by Letitia James, Attorney General of the State of New York, respectfully submit this Memorandum of Law in Support of Their Motions in Limine. Plaintiffs' motions in limine pertain to both the evidence relating to the jury's determination of liability for claims under New York law against the corporate Defendants, as well as the evidence relating to the Court's determination of liability for claims under FTC law against the corporate and individual Defendants, which will in large part be based upon the jury's verdict.

I. INTRODUCTION

Plaintiffs allege that Defendants deceptively represented that their Prevagen products: 1) improve memory; 2) improve memory within 90 days; 3) reduce memory problems associated with aging; and 4) provide other cognitive benefits, including, but not limited to, healthy brain function, a sharper mind, and clearer thinking ("Challenged Efficacy Claims"). Compl. (ECF No. 1) ¶¶ 36-38, 42-45. Plaintiffs also allege that Defendants deceptively represented that such claims for Prevagen products are clinically shown (collectively with the Challenged Efficacy Claims, "Challenged Claims"). *Id.* ¶¶ 39-41, 42-45.

Plaintiffs move to exclude evidence and argument concerning whether Plaintiffs: 1) have evidence relating to consumer perception, net impression, advertising or marketing interpretation, or Prevagen's marketing; or 2) have conducted scientific research or human clinical research on Prevagen. Plaintiffs are neither required to offer extrinsic evidence about consumers, advertising, or marketing (Motion in Limine 1) nor are they required to conduct scientific or clinical research on Prevagen (Motion in Limine 2). Therefore, the Court should preclude such evidence and argument.

In addition, because the Court previously determined that Defendants' proposed expert witness, Dr. Mindy Kurzer, cannot draw an ultimate conclusion as to whether Prevagen impacts cognition or memory, all her testimony on Vitamin D should be excluded (Motion in Limine 3). Plaintiffs also request that Defendants be precluded from offering evidence or argument regarding the FTC staff-issued document, Dietary Supplements: An Advertising Guide for Industry ("FTC Guidance" or "Guidance"), because this evidence would be irrelevant, would constitute impermissible legal opinion, and would serve only to confuse the jury (Motion in Limine 4). Defendants' expert witnesses also should be precluded from offering any opinions regarding the amount and type of scientific evidence required to substantiate the claims challenged (Motion in Limine 5) because any opinions they would offer on that topic, other than opinions on the proper legal standard (which the Court already prohibited), would constitute impermissible new opinions.

Any evidence and argument concerning Defendants' good faith (Motion in Limine 6) and reliance on advice of counsel (Motion in Limine 7) should be excluded because neither good faith nor advice of counsel are viable defenses to liability and Defendants have blocked discovery by asserting the attorney-client privilege. Similarly, evidence and argument that have no bearing on the issues before the jury, including the research or advertising practices of other companies (Motion in Limine 8), the U.S. Food and Drug Administration's ("FDA") approval of Aduhelm (Motion in Limine 9), and the existence of private litigation involving Prevagen, including the *Collins* class action (Motion in Limine 10), should be barred. Evidence and argument relating to the monetary relief sought in this action should also be excluded, as monetary relief is not at issue during the liability phase (Motion in Limine 11).

II. LEGAL STANDARD FOR A MOTION IN LIMINE

A motion in limine is intended "to aid the trial process by enabling the Court to rule in advance of trial on the relevance of certain forecasted evidence, as to issues that are definitely set for trial, without lengthy argument at, or interruption of, the trial." *Palmieri v. Defaria*, 88 F.3d 136, 141 (2d Cir. 1996) (internal quotation marks and citation omitted). "The Federal Rules of Evidence provide that only relevant evidence is admissible." *United States v. Raines*, No. 22-CR-18-02, 2023 WL 6211980, at *2 (S.D.N.Y. Sept. 25, 2023); Fed. R. Evid. 402. Under Rule 401, "[e]vidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. "Irrelevant evidence is not admissible." Fed. R. Evid. 402; *see also Chamilco v. Wild Edibles, Inc.*, No. 16 CV 2848, 2017 WL 11567936, at *1 (S.D.N.Y. Dec. 1, 2017). And under Rule 403, evidence may be excluded if "its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403; *see also Gerber v. Computer Assocs. Int'l*, 303 F.3d 126, 137 (2d Cir. 2002) (court has "'broad discretion to weigh the probative value of the evidence against the negative factors'") (citing *Liz v. Canarozzi*, 142 F.3d 83, 88 (2d Cir. 1998)).

III. MOTION IN LIMINE 1: DEFENDANTS SHOULD BE PRECLUDED FROM ARGUING OR OFFERING EVIDENCE THAT PLAINTIFFS HAVE NOT PROFFERED EXTRINSIC EVIDENCE ABOUT CONSUMERS, ADVERTISING, OR MARKETING

Plaintiffs request that Defendants be precluded from offering any evidence or argument that Plaintiffs have not proffered extrinsic evidence relating to consumer perception, net impression, advertising or marketing interpretation, or Prevagen's marketing. *See* Joint Pretrial Order (ECF No. 300) at 52 (Defs.' Proposed Findings of Fact ¶¶ 21-24); Woo Decl. Ex. 1 (Defs.'

Designations of the Dep. Tr. of Rosemary Rosso) at 2 (designating pages and lines 97:21-98:21, 169:21-170:5, and 170:14-173:3); Ex. 2 (Rosso Dep. Tr.) at 97:21-98:21, 169:21-170:5, and 170:14-173:3. Such evidence and argument are irrelevant and would be unfairly prejudicial. *See* Fed. R. Evid. 401, 402, 403.

It is well established that "[i]f the advertisement explicitly states or clearly and conspicuously implies a claim, the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim." *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 958 (N.D. Ill. 2006) ("Where implied claims are conspicuous and reasonably clear from the face of the advertisements, extrinsic evidence is not required.") (internal quotation marks omitted);[1] *see also FTC v. FleetCor Techs*., 620 F. Supp. 3d 1268, 1295 (N.D. Ga. 2022) (stating that "where the advertisement's claim is explicit, or where it is clearly and conspicuously implied, no extrinsic evidence — in the form of consumer surveys or otherwise — is required to ascertain whether the representation was made") (internal quotation marks and brackets omitted); *FTC v. Alcoholism Cure Corp.*, No. 3:10-cv-266-J-34JBT, 2011 WL 13137951, at *25 (M.D. Fla. Sept. 16, 2011) ("Indeed, consumer survey evidence is not required to support a finding that an advertisement has a tendency to deceive."), *aff'd sub nom. FTC v. Krotzer*, No. 12-14039-AA, 2013 WL 7860383 (11th Cir. May 3, 2013); *FTC v. Medlab*, 615 F. Supp. 2d 1068, 1077-78 (N.D. Cal.

[1] FTC case law is given great weight in construing statutory fraud under New York Executive Law § 63(12) and deceptive practices and false advertising under New York General Business Law ("GBL"). *See People v. Applied Card Sys., Inc.*, 805 N.Y.S.2d 175, 178 (App. Div. 2005) ("recognizing that the interpretations of the Federal Trade Commission Act (*see* 15 U.S.C. § 45 *et seq*.) are useful in determining the aforementioned violations under both the Executive Law and General Business Law"); *see also State v. Feldman*, 210 F. Supp. 2d 294, 302 (S.D.N.Y. 2002); *Oswego Laborers' Loc. 214 Pension Fund v. Marine Midland Bank*, 647 N.E.2d 741, 744-45 (N.Y. 1995); *State v. Colo. State Christian Coll.*, 346 N.Y.S.2d 482, 487 (Sup. Ct. 1973).

2009) ("'Courts, including the Supreme Court, have uniformly rejected imposing . . . a requirement [to present consumer survey evidence] on the FTC, . . . and we decline to do so as well.'") (brackets in original); *People v. Orbital Pub. Grp., Inc.*, 95 N.Y.S.3d 28, 29-30 (App. Div. 2019) (evidentiary hearing not required where court could determine "as a matter of law" that solicitations were materially misleading based on their "overall misleading impression"). Indeed, as the Court previously stated in this case, "[t]he lack of evidence of consumer perception does not mean finding that the challenged statements were not misleading." Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 16. Plaintiffs have no burden to present extrinsic evidence on any aspect of marketing or advertising for Prevagen.

Extrinsic evidence is necessary only for implied claims that are "barely discernable." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1189. For example, the *Medlab* court concluded that "even if the representations were implied, [the] advertisements [at issue] are capable of only one interpretation. The FTC does not need to present consumer survey data in order to prove what is obvious to any rational reader: these advertisements represent that defendants' product achieves dramatic weight loss for anyone without the discomfort of diet and exercise." 615 F. Supp. 2d at 1078. Like in *Medlab*, extrinsic evidence is not needed in this case. At trial, Plaintiffs intend to introduce only advertisements in which the Challenged Claims are express or clearly and conspicuously implied — at the opposite end of the spectrum from "barely discernable." For example, Prevagen product packaging and labels have stated it "Improves Memory" since 2012. Olson Decl. (ECF No. 224) ¶¶ 25-30, Ex. D (ECF No. 224-4) at QUI-FTCNY-00005231, Ex. E (ECF No. 224-5) at QUI-FTCNY-00013352. Evidence that Plaintiffs have not proffered extrinsic evidence on consumer perception, net impression, advertising or marketing

interpretation, or Prevagen's marketing would therefore have no tendency to make more or less probable what claims were communicated in advertisements or whether the claims were substantiated. *Pac. Life Ins. Co. v. Bank of New York Mellon*, 571 F. Supp. 3d 106, 114 (S.D.N.Y. 2021) (stating that "[u]nder the Federal Rules of Evidence, evidence is relevant if it has a 'tendency to make a fact more or less probable than it would be without the evidence'").

Additionally, any probative value would be substantially outweighed by the danger of unfair prejudice, misleading the jury, confusing the issues, and wasting the jury's time because of the risk that the jury would be confused or misled about whether Plaintiffs were required to show this type of evidence at trial. *See* Fed. R. Evid. 403. The jury's determination of whether the Challenged Claims were made should not be influenced by evidence or argument that Plaintiffs failed to present extrinsic evidence of ad meaning or consumer impression. *Perry v. Ethan Allen, Inc.*, 115 F.3d 143, 151 (2d Cir. 1997) (stating that unfair prejudice would result from "evidence [that] has 'an undue tendency to suggest decision on an improper basis'" (citing Fed. R. Evid. 403, adv. comm. notes)). Such argument or evidence would serve no purpose other than to improperly suggest to the jury that Plaintiffs acted wrongly in failing to present extrinsic evidence, when Plaintiffs are not required to possess or present such evidence under relevant case law. *See Highland Cap. Mgmt. v. Schneider*, 551 F. Supp. 2d 173, 192 (S.D.N.Y. 2008) (precluding a party from "coloring its case and wasting the jury's time with misleading and confusing testimony and evidence").

Because it would be irrelevant, unfairly prejudicial, confuse the issues, a waste of time, and mislead the jury for Defendants to argue that Plaintiffs did not present extrinsic evidence on consumer perception, net impression, advertising or marketing interpretation, or Prevagen's marketing, the Court should bar Defendants from making this argument or offering related

evidence at trial.

IV. MOTION IN LIMINE 2: THE COURT SHOULD REJECT DEFENDANTS' ATTEMPT TO REQUIRE PLAINTIFFS TO PUT FORTH SCIENTIFIC OR CLINICAL RESEARCH

Plaintiffs request that Defendants be precluded from arguing or introducing evidence that Plaintiffs have not conducted scientific research or human clinical research concerning apoaequorin or Prevagen. *See* Joint Pretrial Order (ECF No. 300) at 58-60, 66-68 (Defs.' Proposed Findings of Fact ¶¶ 60-66, 96-97, 104); Woo Decl. Ex. 1 (Defs.' Designations of the Dep. Tr. of Rosemary Rosso) at 2 (designating pages and lines 97:21-98:21); Ex. 2 (Rosso Dep. Tr.) at 97:21-98:21. At issue in this case is the adequacy of *Defendants*' purported substantiation for their advertising claims at the time of dissemination. *See, e.g.*, *FTC v. Quincy Bioscience Holding Co., Inc*., 753 F. App'x 87, 89 (2d Cir. 2019) (finding a plausible claim of deception in light of Defendants' clinical trial results). "Defendants have the burden of establishing what substantiation they relied on for their product claims." *QT, Inc*., 448 F. Supp. 2d at 959. Plaintiffs are not required to "conduct or present clinical studies showing that the product does not work as claimed." *Id.*; *see also FTC v. Wellness Support Network, Inc*., No. 10-CV-04879-JCS, 2014 WL 644749, at *15 (N.D. Cal. Feb. 19, 2014) (same), *Alcoholism Cure Corp*., 2011 WL 13137951, at *26 (same). As such, whether or not Plaintiffs conducted scientific or clinical research is wholly irrelevant to this case — evidence or argument on that topic would have no tendency to make any fact more or less probable and would be of no consequence in determining the action. *See* Fed. R. Evid. 401; *see also* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."). Even if there were any probative value to such evidence and argument, it would be outweighed by the confusion, unfair prejudice, and waste of time that would result from prompting the jury to wonder (incorrectly) about whether Plaintiffs should in fact have presented

affirmative research or studies. *See* Fed. R. Evid. 403; *Highland Cap. Mgmt*., 551 F. Supp. 2d at 192 (excluding evidence and argument in limine would "help the jury focus on . . . issues central to the case"). The Court should preclude Defendants from presenting evidence and argument that Plaintiffs and their experts have not conducted affirmative research or studies.

V. MOTION IN LIMINE 3: DR. KURZER'S TESTIMONY RELATING TO VITAMIN D SHOULD BE EXCLUDED

Because the Court previously determined that Dr. Kurzer "may not draw an ultimate conclusion as to whether Prevagen impacts cognition or memory," her proposed testimony on Vitamin D would be irrelevant, cause unfair prejudice, mislead the jury, and waste time, and therefore should be excluded. Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 19.

Under Federal Rule of Evidence 702, the Court must determine whether the expert testimony "will help the trier of fact to understand the evidence or to determine a fact in issue." *Pac. Life Ins. Co.*, 571 F. Supp. 3d at 114. "This inquiry looks primarily to whether the testimony is relevant." *Id.* "'[E]vidence is relevant if (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action.'" *Better Holdco, Inc. v. Beeline Loans, Inc.*, No. 20 Civ. 8686, 2023 WL 2711417, at *19 (S.D.N.Y. Mar. 30, 2023) (quoting Fed. R. Evid. 401). "'Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.'" *Pac. Life Ins.*, 571 F. Supp. 3d at 114 (quoting *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 591-92 (1993)). In her expert report, Dr. Kurzer offers opinions relating to Vitamin D, including interpretations of scientific studies. Graham Decl. Ex. R (ECF No. 225-18), Kurzer Aff. Report ¶¶ 58-78; *see also* Joint Pretrial Order (ECF No. 300) at 67-68 (Defs.' Proposed Findings of Fact ¶¶ 98-103). Because Dr. Kurzer cannot "draw an

ultimate conclusion as to whether Prevagen impacts cognition or memory," she would be unable to opine on whether the scientific evidence on Vitamin D shows that Prevagen, which contains Vitamin D, impacts memory or cognition. Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 19. Absent an opinion on Vitamin D relating to the ultimate conclusion from Dr. Kurzer,[2] her testimony about the design or conduct of Vitamin D studies would not be helpful to the jury because these facts about the studies by themselves are not of consequence in determining the ultimate issue — does Prevagen improve memory or cognition — and are therefore irrelevant. *Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.") (internal quotation marks omitted).

Furthermore, Dr. Kurzer's testimony should be excluded under Rule 403. Fed. R. Evid. 403. "The Rule 403 inquiry is particularly important in the context of expert testimony, 'given the unique weight such evidence may have in a jury's deliberations.'" *Pac. Life Ins.*, 571 F. Supp. 3d at 114 (citing *Nimley v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005)); *see also In re Elysium Health-ChromaDex Litig.*, No. 17-cv-7394, 2022 WL 421135, at *28 (S.D.N.Y. Feb. 11, 2022) (noting that the expert testimony's little probative value was "'far outweighed by the danger that the jury would accord too much weight to such opinions because they come from the mouth of a . . . professional'") (quoting *Tchatat v. City of New York*, 315 F.R.D. 441, 447 (S.D.N.Y. 2016)). "'Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against

[2] None of Defendants' other experts offer any opinions involving the effect of Vitamin D on memory or cognitive function.

probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses.'" *Nimley*, 414 F.3d at 397 (quoting *Daubert*, 509 U.S. at 595).

Here, Dr. Kurzer's testimony about Vitamin D studies would mislead the jury, cause unfair prejudice, confuse the issues, and waste time. Absent testimony on whether the evidence relating to Vitamin D shows that Prevagen improves memory, which Dr. Kurzer cannot offer pursuant to the Court's Order, Dr. Kurzer's opinions on Vitamin D would potentially cause the jury to reach a conclusion for which there is no evidence. *United States v. Litvak*, 808 F.3d 160, 185-86 (2d Cir. 2015) (excluding expert testimony that had no bearing on the ultimate issues at trial); Op. & Order on Mot. For Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 19. For example, Dr. Kurzer's testimony that a Vitamin D study was well designed or had statistically significant results on measures of cognitive function could mislead the jury. *See SEC v. Tourre*, 950 F. Supp. 2d 666, 678 (S.D.N.Y. 2013) (excluding expert evidence because, even with a cautionary instruction, expert testimony might cause the jury to reach an impermissible conclusion). Dr. Kurzer's testimony about the design or results of a scientific study could cause the jury to improperly infer that such evidence shows that Prevagen improves memory, which Dr. Kurzer cannot opine on. *See United States v. Gatto*, 986 F.3d 104, 118 (2d Cir. 2021) (finding that the court appropriately excluded expert evidence that "might have clouded the issue for the jury"); *Dunham v. Lobello*, No. 11-cv-1223, 2023 WL 3004623, at *5 (S.D.N.Y. Apr. 19, 2023) ("Prejudicial effect may be created by the tendency of the evidence to prove some adverse fact not properly in issue or unfairly to excite emotions.") (internal quotation marks and brackets omitted); *Katt v. City of New York*, 151 F. Supp. 2d 313, 353-54 (S.D.N.Y. 2001) (noting that "[u]nfairness may be found in any form of evidence that may cause a jury to base its decision on something other than the established propositions in the case") (internal

quotation marks omitted). Therefore, Dr. Kurzer's testimony on Vitamin D should be excluded because it would not be relevant and would cause unfair prejudice, mislead the jury, confuse the issues, and waste time.

VI. MOTION IN LIMINE 4: THE COURT SHOULD PRECLUDE EVIDENCE AND ARGUMENT REGARDING THE FTC GUIDANCE

The Court should preclude Defendants from offering evidence or argument regarding the FTC Guidance, as such evidence and argument would be irrelevant, constitute impermissible legal opinion, and serve only to confuse the jury.

The Federal Rules provide that only relevant evidence — evidence of consequence in determining an action — is admissible. Fed. R. Evid. 401, 402. Evidence regarding the FTC Guidance — a document issued by FTC staff to assist marketers in understanding federal advertising law — would not be relevant to what the Court has identified as the critical issue to be determined at trial: whether Defendants possessed sufficient scientific evidence to support the Challenged Claims. Furthermore, any testimony regarding the meaning of the Guidance's content would constitute impermissible legal opinion. And, as it is the Court alone who must identify and explain the relevant law, any evidence about a document explaining the legal standard in this case would serve only to mislead and confuse the jury.

The FTC Guidance is a document issued by FTC staff that attempts to explain the law to marketers. *See* Graham Decl. Ex. F (ECF No. 225-6), FTC Guidance at QUI-FTCNY-00189204 to QUI-FTCNY-00189205. Evidence regarding the Guidance therefore would not be relevant to what the Court has identified as the critical issue to be determined at trial: whether Defendants possessed sufficient scientific evidence to support the Challenged Claims. As this Court stated:

> *The critical question for trial does not turn on an interpretation of the FTC Guidance. The question for trial is whether defendants had the necessary scientific evidence to support the claims defendants made while advertising*

> *Prevagen.* That is an issue for the experts in the field and is not necessarily limited or expanded in scope, as discussed below, by experts' reference to the FTC Guidance.

Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 15 (emphasis added). To assess whether Defendants possessed sufficient scientific evidence to support the Challenged Claims, the expert witnesses in this case must apply the standards of the relevant scientific fields. *See Daniel Chapter One v. FTC*, 405 F. App'x 505, 506 (D.C. Cir. 2010); *FTC v. Roca Labs, Inc.*, 345 F. Supp. 3d 1375, 1387 (M.D. Fla. 2018); *FTC v. COORGA Nutraceuticals Corp.*, 201 F. Supp. 3d 1300, 1309 (D. Wyo. 2016). Such a scientific analysis would not involve reference to a document issued by FTC staff to explain federal law. Accordingly, evidence regarding the Guidance — including testimony relating to any expert's awareness, use, or understanding of the document — would be irrelevant and would not assist the trier of fact.

Furthermore, any testimony regarding the meaning of the Guidance's content, in addition to being irrelevant, would constitute impermissible legal opinion. The law is clear that expert testimony purporting to identify or explain the applicable law or legal standards, or that offers legal conclusions, is inadmissible. *See, e.g.*, *Hygh v. Jacobs*, 961 F.2d 359, 363 (2d Cir. 1992); *United States v. Scop*, 846 F.2d 135, 140 (2d Cir. 1988); *Marx & Co. v. Diners' Club, Inc.*, 550 F.2d 505, 510-12 (2d Cir. 1977); *Torres v. County of Oakland*, 758 F.2d 147, 150 (6th Cir. 1985); *Strong v. E.I. DuPont de Nemours Co.*, 667 F.2d 682, 685-86 (8th Cir. 1981). The Guidance is not a scientific document, and expert testimony regarding its content — an explanation of the law — would not constitute "scientific knowledge," as required under Federal Rule of Evidence 702 and *Daubert*, 509 U.S. at 589-90. Rather, such testimony would constitute opinion regarding the legal standard in the case, which this Court has found to be improper. *See*

Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 18 (prohibiting Drs. Schwartz, Katz, and Wei "from opining on the proper legal standard").

Finally, as it is the Court that will explain the relevant law to the jury, testimony regarding the Guidance — a document designed to explain federal law — would only confuse and mislead the jury. *See United States v. Stewart*, 433 F.3d 273, 311 (2d Cir. 2006) ("[A]n opinion that purports to explain the law to the jury trespasses on the trial judge's exclusive territory."); Fed. R. Evid. 403 (court may exclude even relevant evidence whose probative value is substantially outweighed by a danger of confusing the issues or misleading the jury). For instance, testimony regarding expert witnesses' use or understanding of the Guidance would confuse the jury about which explanation of the law — the experts' or the Court's — it should follow. Such testimony thus would create a serious risk that the jury would misunderstand the law and render a verdict on an improper basis. *See Gatto*, 986 F.3d at 117-18 (affirming the district court's exclusion of evidence because it was not helpful and would only serve to entice the jury to base its decision on an improper defense); *United States v. Ray*, No. 20-cr-110, 2022 WL 292800, at *14 (S.D.N.Y. Feb. 1, 2022) (excluding expert testimony in light of "distinct danger" it would confuse jury, including by creating a "substantial risk" the jury would use it for "an impermissible purpose in deliberations") (internal quotation marks omitted).[3] The Court

[3] Testimony from Defendants' experts regarding the Guidance would confuse the jury for the additional reason that the experts mistakenly characterize and interpret the Guidance. As set out in Plaintiffs' *Daubert* filings, Defendants' experts misinterpret the Guidance and cherry-pick portions of the document that they believe support their opinions, while ignoring portions that undermine their opinions. *See* Pls.' Mem. of Law in Supp. of Their Mot. to Exclude the Test. of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler (ECF No. 304) at 13-14; Pls.' Reply in Supp. of Their Mot. to Exclude the Test. of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler (ECF No. 318) at 15-16.

therefore should preclude Defendants from offering any evidence or argument regarding the FTC Guidance.

VII. MOTION IN LIMINE 5: DEFENDANTS' EXPERTS SHOULD BE PRECLUDED FROM OPINING ON THE AMOUNT AND TYPE OF EVIDENCE NEEDED TO SUBSTANTIATE THE CHALLENGED CLAIMS

The Court should preclude Defendants' expert witnesses from offering any opinion on the amount and type of scientific evidence required to substantiate the Challenged Claims, including any opinion that a randomized, controlled trial ("RCT") is not required. Defendants' experts' opinions on this issue, as reflected in their reports, are based only on the experts' flawed understandings of the law, which the Court has ruled are inadmissible. Having failed to disclose any other basis for their opinions in their expert reports, the experts should be precluded from offering any opinions or testimony on the issue, including any testimony that their opinions are actually based on their scientific knowledge, experience, or expertise.

The Federal Rules of Civil Procedure require expert reports to contain "a complete statement of all opinions the witness will express *and the basis and reasons for them*." Fed. R. Civ. Pro. 26(a)(2)(B)(i) (emphasis added). If a party fails to provide information required by Rule 26(a), "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. Pro. 37(c)(1); *see also Ferriso v. Conway Org.*, No. 93 Civ. 7962, 1995 WL 580197, at *1-2 (S.D.N.Y. Oct. 3, 1995) (upholding decision of magistrate judge to exclude expert testimony on opinion not included in expert report).

The reports of Defendants' experts make clear that their opinions on the amount and type of evidence needed to substantiate the Challenged Claims are based only on their purported understanding of the law, and not on the standards of their scientific fields or their scientific

knowledge, expertise, or experience. Dr. Schwartz, for example, includes a section in his rebuttal report titled "Level of Evidence Required for Dietary Supplement Manufacturers to Substantiate Structure-Function Marketing Claims," in which he purports to "provide a brief review of the level of evidence required by the FTC as set forth in its own guidance document, Dietary Supplements: An Advertising Guide for Industry (the 'Advertising Guide') specifying the level of evidence required for dietary supplement manufacturers to substantiate their structure-function marketing claims." Graham Decl. Ex. X (ECF No. 225-24), Schwartz Rebuttal Report ¶ 10 (footnote omitted). In that section, Dr. Schwartz opines initially that, in his view, "[t]he Dietary Supplement Health and Education Act (DSHEA) provides a framework for manufacturers to make structure-function claims on products that meet the definition for a dietary supplement product." *Id.* ¶ 13. Dr. Schwartz then sets forth his opinions on how the Guidance sets out the required level of substantiation for marketing claims, stating, among other things, that "[t]he FTC's Advertising Guide also does not require a placebo-controlled human clinical trial to substantiate dietary supplement structure-function claims." *Id.* ¶ 17. At no point does Dr. Schwartz reference or apply the standards of his educational fields, neuroscience and psychology, to explain what substantiation requirements are appropriate for the Challenged Claims.

Dr. Katz similarly makes clear that he bases his opinion on the amount and type of evidence needed to substantiate the Challenged Claims not on science, but on his flawed understanding of federal statutes and what he mistakenly believes the FTC has communicated in the Guidance. Dr. Katz states specifically in his rebuttal report that a "relevant question" in the case is whether "the body of evidence (including mechanistic studies, animal research and human research) meet or exceed the requirements set forth under the DSHEA and relevant FTC

and FDA guidelines to substantiate the Challenged Claims . . . ." Graham Decl. Ex. P (ECF No. 225-16), Katz Rebuttal Report ¶ 10. In the report's section on "the appropriate standard of review for dietary supplement products," Dr. Katz states that the applicable "regulatory framework" depends upon the classification of the substance at issue, and that "Prevagen is classified as a dietary supplement, a category that is distinguished by DSHEA." *Id.* ¶ 18. Dr. Katz opines further that the FTC Guidance "does not require human clinical trials" and that the fact that Defendants conducted an RCT suggesting a clinical benefit "greatly exceeds the required standard to market a dietary supplement under DSHEA and the FTC's own Guidance." *Id.* ¶¶ 20, 23.

Dr. Wei, in opining on the amount and type of evidence required to substantiate the Challenged Claims, also fails to apply the standards of any scientific field, basing his opinion instead on the FTC Guidance. Dr. Wei criticizes Plaintiffs' experts Drs. Sano and Wittes for failing to apply "the FTC's 'flexible' standard for assessing claims for dietary supplements" and states that the Guidance "makes clear" that "competent and reliable scientific evidence" is "not the same standard as required for drug trials. In particular, randomized, clinical trials are not required." Graham Decl. Ex. Z (ECF No. 225-26), Wei Rebuttal Report at 3 and ¶¶ 13, 14 (emphases in original). Dr. Wei states further that "[v]iewing the Madison Memory Study through the 'flexible' lens suggested by the FTC, it is my professional opinion that it more than qualifies as one piece of competent and reliable evidence of the efficacy of Prevagen."[4] *Id.* ¶ 17.

[4] Although he did not focus on the type or amount of evidence needed to substantiate the Challenged Claims to the extent Drs. Schwartz, Katz, and Wei did, Dr. Gortler cited the Guidance as support for his statement that "all that is required scientifically speaking" for the marketing of a dietary supplement is "'truthful, not misleading, and substantiated' information." Matuschak Decl. Ex. H (ECF No. 305-8), Gortler Rebuttal Report ¶ 40 & n.9 (quotation omitted). Such testimony should also be excluded.

Defendants' experts' opinions regarding the evidence required to substantiate the Challenged Claims thus are based only on their flawed understandings of the law, which the Court has already found to be inadmissible. *See* Op. & Order on Mot. for Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 18 (prohibiting Drs. Schwartz, Katz, and Wei, "from opining on the proper legal standard"). Any testimony resting on any other grounds would constitute impermissible new information and opinion that Defendants failed to disclose in their experts' reports. Furthermore, Defendants' failure to disclose any other bases for their experts' opinions would be neither justified nor harmless. Plaintiffs filed their case in 2017 and the key issues in the matter, including the evidence required to substantiate the Challenged Claims, have long been known. Expert discovery ended two years ago and, with trial likely to commence in a few months, Plaintiffs would be prejudiced by not having the ability to take discovery regarding any alternative bases for the experts' opinions.

Accordingly, as the reports of Defendants' experts failed to include any permissible basis for their opinions on the amount and type of evidence needed to substantiate the Challenged Claims, the Court should preclude the experts from offering testimony on the issue.

VIII. MOTION IN LIMINE 6: THE COURT SHOULD EXCLUDE ANY TESTIMONY AND ARGUMENTS ABOUT GOOD FAITH

Whether Defendants acted in good faith is not relevant to any issue in the liability phase of this case. Defendants should therefore be prohibited from presenting any testimony concerning any of their witnesses' subjective good faith, and any argument concerning Defendants' good faith.[5]

[5] Plaintiffs are not contesting Defendants' ability to present evidence concerning their efforts to substantiate their advertising claims (subject to objections on other grounds as stated in the parties' Joint Pretrial Order (ECF No. 300) and elsewhere) but are contesting Defendants' ability to characterize any such efforts to substantiate their claims as evidence of their "good faith."

Defendants themselves acknowledged that good faith is not relevant in determining liability in opposing Plaintiffs' motion to strike certain affirmative defenses. Op. & Order on Mot. to Strike (ECF No. 99) at 7 ("Defendants acknowledge that good faith is not relevant in determining whether they engaged in deceptive or fraudulent conduct."). *See also, e.g.*, *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1495 (1st Cir. 1989) ("The FTC need not prove a willful, knowing[,] or deliberate act in order to prove a violation of 15 U.S.C. § 45.") (citing *Chrysler Corp. v. FTC*, 561 F.2d 357, 363 (D.C. Cir. 1977) ("intent to deceive is not a required element for a section 5 violation")); *FTC v. Five-Star Auto Club, Inc.*, 97 F. Supp. 2d 502, 526 (S.D.N.Y. 2000) (intent to defraud or deceive, or bad faith, not necessary to establish a violation of Section 5 of the FTC Act); *People v. Gen. Elec. Co.*, 756 N.Y.S.2d 520, 523 (App. Div. 2003) ("neither bad faith nor scienter is required under New York Executive Law § 63(12)"); *People v. Wilco Energy Corp*., 728 N.Y.S.2d 471, 473 (App. Div. 2001) (noting that "intent to defraud is not a requirement for liability" under N.Y. General Business Law §§ 349 and 350); *see also, e.g.*, *FTC v. Moses*, 913 F.3d 297, 307 (2d Cir. 2019) (agreeing with other circuits that "knowledge may be established by showing that the individual defendant . . . was recklessly indifferent to [the conduct's] deceptiveness, or had an awareness of a high probability of deceptiveness and intentionally avoided learning of the truth"); *FTC v. Direct Benefits Grp*., *LLC*, No. 6:11-CV-1186-ORL-28, 2013 WL 3771322, at *20 (M.D. Fla. July 18, 2013) (rejecting Defendants' contention that bad faith is required to be held personally liable).

Indeed, Defendants asserted good-faith affirmative defenses only with respect to Plaintiffs' claim for permanent injunctive relief, as they clarified in briefing Plaintiffs' motion to strike. Corporate Defs.' Br. in Opp. to Pls.' Mot. to Strike Affirmative Defenses (ECF No. 88) at 14 (the Corporate Defendants "did not assert good faith as a defense to liability"); Def.

Underwood's Br. in Opp. to Pls.' Mot. to Strike Affirmative Defenses (ECF No. 87) at 2 (adopting and incorporating the argument in the Corporate Defendants' brief); *see also* Corporate Defs.' Answer (ECF No. 73) at 9 (alleging as a tenth defense that good faith "prohibits Plaintiffs from obtaining any injunctive relief"); Def. Underwood's Answer (ECF No. 74) at 10 (same). The Court declined to strike Defendants' good-faith affirmative defenses on the grounds that good faith could be potentially relevant to Plaintiffs' entitlement to injunctive relief but noted that "good faith in conducting clinical studies and advertising the results is not a defense to liability." Op. & Order on Mot. to Strike (ECF No. 99) at 7.

Testimony concerning the subjective good faith of any of Defendants' witnesses and any argument concerning good faith, a lack of bad faith, a belief that their advertising claims were substantiated, a lack of intent to deceive, or any variation thereof in the phase(s) of trial directed toward determining Defendants' liability would serve only to confuse the issues, mislead the jury, prejudice Plaintiffs, and waste the Court's and the jury's time. *See* Fed. R. Evid. 403. Any such argument and testimony should be excluded. *See, e.g.*, *FTC v. Pioneer Enters., Inc.*, No. CV-S-92-615-LDG(RJJ), 1992 WL 372350, at *4 (D. Nev. Nov. 12, 1992) (excluding in limine proposed testimony about good faith and advice of counsel).

IX. MOTION IN LIMINE 7: THE COURT SHOULD EXCLUDE ANY EVIDENCE AND ARGUMENT ABOUT THE ADVICE OF COUNSEL

Plaintiffs request that Defendants be precluded from introducing evidence and making arguments concerning the advice of counsel. The Court should prohibit them from doing so at the jury trial and at any separate evidentiary hearing concerning Mr. Underwood's individual liability before the Court. The advice of counsel is not relevant to any Defendant's liability. In addition, having resisted discovery into any advice provided by their counsel, Defendants may not now use the advice of counsel as a shield from liability.

An argument that a defendant relied on the advice of counsel is tantamount to an argument that a defendant acted in good faith. As such, testimony and argument concerning the advice of counsel is as irrelevant to the liability phase(s) of this action as any other good faith arguments would be. *See supra* at 18-20. This is true with respect to individual liability as well as corporate liability: "reliance on advice of counsel is not a valid defense on the question of knowledge required for individual liability." *FTC v. Cyberspace.com LLC*, 453 F.3d 1196, 1202 (9th Cir. 2006) (brackets and internal quotation marks omitted). The "blessing of an attorney" cannot make a deceptive statement truthful or "sanction something that the defendants should have known was wrong." *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 575 (7th Cir. 1989), *overruled on other grounds by FTC v. Credit Bureau Ctr., LLC*, 937 F.3d 764 (7th Cir. 2019); *see also, e.g.*, *FTC v. Swatsworth*, No. 3:17-CV-340-GCM, 2018 WL 4016312, at *6 (W.D.N.C. Aug. 22, 2018) (finding individual defendant liable under the FTC Act as a matter of law despite representations that the relevant documents had been reviewed by attorneys).

Moreover, it is well established that "the attorney-client privilege cannot at once be used as a shield and a sword." *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991); *see also, e.g.*, *In re Sims*, 534 F.3d 117, 132 (2d Cir. 2008). "A [party] may not use the privilege to prejudice his opponent's case or to disclose some selected communications for self-serving purposes." *Troublé v. Wet Seal, Inc*., 179 F. Supp. 2d 291, 304 (S.D.N.Y. 2001) (precluding evidence about advice of counsel at trial because defendant waived defense "by objecting, based on the attorney-client privilege, to [plaintiff's] discovery requests"). Failure to make a full disclosure on the advice of counsel during discovery "constitutes a waiver" of the advice-of-counsel defense. *See Arista Records LLC v. Lime Grp. LLC*, No. 06 Civ. 5936, 2011 WL 1642434, at *2 (S.D.N.Y. Apr. 20, 2011) (internal quotation marks omitted).

Here, Defendants repeatedly cautioned witnesses not to reveal the content of attorney-client communications or instructed them not to answer questions on the same basis — and the Court sustained the privilege objections that Plaintiffs challenged. *See* Op. & Order (ECF No. 127) (quashing subpoena to economic consulting firm and upholding privilege objections and instructions not to answer concerning 2015-2016 analyses of Madison Memory Study ("MMS") and any follow-up studies to the MMS); *see also, e.g.*, Woo Decl. Ex. 3 (Tr. of Aug. 20, 2020 Dep. of Mark Underwood) at 30:20-31:8 (instruction not to answer why pepsin digestion assay study was done); 83:7-15 (instructions not to answer concerning board communications regarding FDA warning letter); 101:20-102:13 (caution not to reveal privileged communications concerning change to Prevagen label). The Court should preclude any evidence and argument concerning the advice of counsel before the jury and at any subsequent evidentiary hearing on liability before the Court. *Pioneer Enters.*, 1992 WL 372350, at *4 (testimony "concerning the defendants' lack of bad faith or their efforts to comply with federal and state laws is irrelevant and will not be allowed").

X. MOTION IN LIMINE 8: THE COURT SHOULD EXCLUDE AS IRRELEVANT AND PREJUDICIAL ANY EVIDENCE AND ARGUMENT RELATING TO THE RESEARCH OR ADVERTISING PRACTICES OF OTHER COMPANIES

The Court should preclude Defendants from offering evidence and argument describing what is "usual" or "unusual" with respect to the research or advertising practices of other companies, including other companies that market and sell dietary supplements, herbal remedies, and vitamins that are different from Prevagen and intended for different purposes. The Court should also prevent Defendants and their experts from arguing that the studies of these other companies often include analyses of subgroups of the studies' data, including analyses performed after the fact or *post hoc*, and therefore, Defendants should not be held liable under

FTC or New York law. Because every element in the claims brought by the FTC and the NYAG relates to Defendants' conduct, the purported research and advertising practices of other companies have no bearing on Plaintiffs' claims and should be excluded as irrelevant and prejudicial.

Dr. David Katz, an internal medicine doctor by training, contends, "Given the dearth of human clinical trials conducted on popular herbal and nutritional supplements, and considering that most other manufacturers/marketers do not (and are not required to) invest in, conduct or publish scientific research on their products, the effort and expense that Quincy Bioscience has invested in research on apoaequorin is laudable." Graham Decl. Ex. P (ECF No. 225-16), Katz Rebuttal Report ¶ 29. He further opines that it is not unusual "for the results of subgroup analysis to form the foundation of clinical recommendations and/or marketing" for dietary supplements, including but not limited to AREDS 2 (vitamins marketed for macular degeneration), L-Theanine (an amino acid marketed for anxiety, stress reduction, and cognitive enhancements), Kava Kava (an herbal remedy marketed for anxiety), and probiotics (supplements marketed for occasional diarrhea and maintenance of digestive health). Graham Decl. Ex. O (ECF No. 225-15), Katz Aff. Report ¶¶ 64-65.

Like Dr. Katz, Dr. David Schwartz, a neuroscientist by training, characterizes Defendants' "research program" as "unusual" for a dietary supplement manufacturer, stating that Quincy's "financial investment" was "considerable" and "significantly more than other dietary supplement manufacturers spend on the development and substantiation of their products." Graham Decl. Ex. X (ECF No. 225-24), Schwartz Rebuttal Report ¶¶ 9, 20. Dr. Schwartz notes that many dietary supplement companies do not support their advertising claims with RCTs and cites as examples dietary supplements that are not just entirely different from Prevagen but are

also marketed for different purposes, including ResVitale, Resveratrol 250 mg (for longevity) and Life Extension Dopa-Mind (for longevity and dopamine levels). *See id.* ¶¶ 22, 40, 44, 50. Dr. Schwartz notes that "there are dietary supplements on the market for which the evidence is mixed and for which systematic reviews have failed to find clear evidence of benefit," again citing as examples products that bear no resemblance to Prevagen and are marketed for different purposes, such as calcium supplements (to prevent fractures) and Ginkgo bilboa (for cognitive benefits). *Id.* ¶¶ 46, 47.

Plaintiffs' lawsuit concerns Defendants' actions, not the actions or inactions of other companies, including other dietary supplement companies. The actions or inactions of other companies have no bearing on this case. *FTC v. Chemence, Inc.*, 209 F. Supp. 3d 981, 985 (N.D. Ohio 2016) ("The FTC's lawsuit concerns [Defendant's] actions, not its competitor's actions. . Every element in a Section 5 claim relates to the conduct of the *defendant* in the lawsuit, not the conduct of other industry participants. Thus, the conduct of other participants in the cyanoacrylate glue industry . . . has no bearing on the FTC's claim.") (emphasis in original). Even if Defendants were able to show that their research practices were typical of or better than the industry standard, it does not follow that the industry-wide practices would not be deceptive under the FTC Act and parallel New York law. *See Consumer Fin. Prot. Bureau v. Navient Corp*, No. 3:17-CV-101, 2018 U.S. Dist. LEXIS 76155, at *20 (M.D. Pa. May 4, 2018). Indeed, any such demonstration would "afford the basis for an argument that such [industry participants] should be dealt with likewise, not that [Defendants] should escape." *Int'l Art Co. v. FTC*, 109

F.2d. 393, 397 (7th Cir. 1940) (finding "immaterial" whether competitors employ the same or similar methods).[6]

In addition to being wholly irrelevant, any evidence or argument about other companies that Defendants and their experts seek to offer would unfairly prejudice and confuse the jury by introducing "alternative and improper grounds for decision on bases other than the pertinent legal standards." *See, e.g.*, *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 545 (S.D.N.Y. 2004) (excluding expert testimony regarding industry ethical standards as unfairly prejudicial). "Other courts have rejected the type of . . . 'everybody else is doing it' justification" that Defendants seek to offer; that is not the applicable standard under the FTC Act and parallel New York law. *See Chemence*, 209 F. Supp. 3d at 985-86; *see also Navient*, 2018 U.S. Dist. LEXIS 76155, at *20; *Aloha Airlines, Inc. v. Civil Aeronautics Bd.*, 598 F.2d 250, 258 (D.C. Cir. 1979) ("Aloha could not justify a violation of [a statute prohibiting unfair or deceptive practices in air transportation] by proof that its competitor also violated that [statute].").

Evidence and argument that compares Defendants to other companies that market different products simply have no bearing on whether Defendants' claims were supported by competent and reliable scientific evidence. Therefore, evidence and argument about the actions, inactions, or understandings of other industry participants is irrelevant to the present matter and would be prejudicial and confusing to the jury. *See* Fed. R. Evid. 401, 402, 403. This suit is against specific Defendants; those Defendants are the only Defendants whose actions are

[6] Further, even if Defendants could demonstrate that other companies have violated the FTC Act and New York law, but have not been prosecuted, that too would be irrelevant to the instant lawsuit. *See Chemence*, 209 F. Supp. 3d at 985; *see also FTC v. Universal-Rundle Corp.*, 387 U.S. 244, 251 (1967) ("even if a petitioner succeeded in demonstrating to the Commission that all of its competitors were engaged in illegal price-discrimination practices identical to its own, and that enforcement of a cease-and-desist order might cause it substantial financial injury, the Commission would not necessarily be obliged to withhold enforcement of the order").

relevant and should be considered. Defendants should thus be precluded from presenting any evidence or argument about the research or advertising practices of other companies, including other dietary supplement companies.

XI. MOTION IN LIMINE 9: THE COURT SHOULD EXCLUDE AS IRRELEVANT ANY EVIDENCE AND ARGUMENT RELATING TO THE FDA'S APPROVAL OF THE DRUG ADUHELM

The Court should exclude as irrelevant any evidence and argument relating to the approval by the FDA of a prescription drug named Aduhelm, which bears no similarity to Prevagen and is intended for a different population — adults suffering from Alzheimer's disease. Graham Decl. Ex. P (ECF No. 225-16), Katz Rebuttal Report ¶¶ 6, 31-36; Ex. X (ECF No. 225-24), Schwartz Rebuttal Report ¶¶ 23-26, 46. Defendants concede that the FDA's "regulatory approval of Aduhelm may not be *directly* relevant to the substantiation of the Challenged Claims," yet, they seek to introduce testimony about how the FDA, a different law enforcement agency, "granted [Aduhelm] accelerated *drug* approval . . . despite substantial disagreement within the scientific community concerning the strength of the evidence and the safety of the drug, among other things, not to mention the small dataset considered by the FDA." Defs' Mem. Law Opp'n Pls.' Mot. Exclude Test. Defs. Experts (ECF No. 315) at 12 (emphases in original). This Court has already ruled that Defendants' "experts may also not opine on the development of the FDA regulatory scheme or on Congress' intent in passing certain laws, such as the Dietary Supplement Health and Education Act." Op. & Order on Mot. For Summ. J. & Mot. to Exclude Expert Test. (ECF No. 331) at 19. In light of the Court's ruling, and Defendants' own concession, Plaintiffs seek to exclude all evidence and argument relating to Aduhelm and the FDA's approval of this prescription drug.

The FDA's approval of Aduhelm and the degree of regulation that Aduhelm would be subjected to by the FDA have no bearing on any of the issues of this case. *See Bristol-Myers Co. v. FTC,* 738 F.2d 554, 559 (2d Cir. 1984) ("Insofar as FDA requirements and regulations are concerned, they simply do not govern this case."); *see also Thompson Med. Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986) (stating that *Bristol-Myers* made it "quite clear" that FDA requirements and evaluations implicated a different regulatory scheme and did not govern an FTC case); *FTC v. Lunada Biomedical*, No. CV-15-3380-MWF, 2015 WL 12911515, at *4-5 (C.D. Cal. Sept. 23, 2015) (noting that FDA requirements and regulations did not apply to advertising claims even when the product at issue was a dietary supplement); *FTC v. Wellness Support Network, Inc.*, No. 10-cv-04879, 2013 WL 5513332, at *10 (N.D. Cal. Oct. 4, 2013) (finding FDA classification of a product irrelevant and excluding testimony of expert who relied on FDA regulations since the proposed testimony did not constitute "scientific knowledge"). This case is not brought under any statute or rule enforced by the FDA and does not involve the FDA's regulatory process for drugs generally or for Aduhelm specifically.

With no probative value, evidence or argument about FDA and Aduhelm would only serve to mislead the jury, confuse the issues, cause unfair prejudice, and lead to undue delay. *See Gatto*, 986 F.3d at 117-18 (affirming the district court's exclusion of evidence because it was not helpful and could only serve to entice the jury to base its decision on an improper defense); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 198 (S.D.N.Y. 2009); Fed. R. Evid. 403. Such evidence or argument would do nothing more than conflate what is required under FTC or New York laws with FDA law and confuse the jury, or lead it to give weight to facts irrelevant to any issues in the case. Plaintiffs therefore request that all evidence and argument relating to Aduhelm and FDA's approval of Aduhelm or other drugs be excluded in its entirety.

XII. MOTION IN LIMINE 10: THE COURT SHOULD EXCLUDE ANY REFERENCES TO ANY PRIVATE LITIGATION ARISING FROM THE ADVERTISING OF PREVAGEN, INCLUDING THE *COLLINS* CLASS ACTION AND SETTLEMENT, AS IRRELEVANT, PREJUDICIAL, AND PROHIBITED UNDER RULE 408

To the extent Defendants intend to introduce testimony or other evidence at trial that would reveal the existence of any private litigation relating to the advertising of Prevagen, including the *Collins* class action and the terms of the settlement in that action, such evidence should be excluded.

Defendants have been sued in multiple private class actions related to the marketing of Prevagen. In June 2020, Defendants agreed to a settlement in the case captioned *Collins v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla.) to resolve all of the then-pending class actions nationwide. Woo Decl. Ex. 4 (Pls.' Am. Unopposed Mot. For Prelim. Approval of Class Action Settlement and Certification of the Settlement Class, *Collins v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla. June 24, 2020), ECF No. 147 [hereinafter "*Collins* Pls.' Unopposed Mot."]) at 5. The *Collins* settlement agreement, which was approved by the district court, included, *inter alia*, monetary relief in the form of partial refunds to a nationwide class of Prevagen purchasers, and injunctive relief that requires either: competent and reliable scientific evidence to substantiate certain claims about Prevagen's effect on memory; or the use of certain disclaimers to qualify such claims. *Id.*, Settlement Agreement and Release (Ex. 1 to *Collins* Pls.' Unopposed Mot.) at 7-8 [hereinafter "Settlement Agreement and Release"].

Defendants have submitted Proposed Findings of Fact that include references to the *Collins* settlement. *See* Joint Pretrial Order (ECF 300) at 68-70 (Defs.' Proposed Findings of Fact ¶¶ 105-109). Also, Defendants have strongly suggested that all of their advertising since the

Collins settlement is lawful because it incorporates disclaimers required in the settlement agreement. *See, e.g.*, Defs.' Trial Br. (ECF 327-2) at 3-4, 12.

A. The Fact that Defendants Settled Private Litigation Relating to the Marketing of Prevagen Is Not Relevant to the Determination of Liability in This Case

Any references to the existence of any private class action or the settlement in *Collins* are irrelevant to the determination of Defendants' liability by the jury or the Court. *See, e.g.*, *Moore v. Rubin*, No. 17-CV-6404 (BMC), 2020 WL 13573582, at *3 (E.D.N.Y. Jan. 31, 2020) ("Courts generally exclude evidence of other lawsuits even if the other lawsuits are related to the case before the court"); *L.A. Printex Indus., Inc. v. Pretty Girl of California, Inc.*, No. 09 Civ. 4206 (KBF), 2012 WL 12886988, at *1 (S.D.N.Y. May 24, 2012) (evidence of other lawsuits was "barred" by Fed. R. Evid. 401 and 403). There is simply no relevance to the fact that Defendants have been involved in other litigation related to their advertising of Prevagen, given that there are no admissions of liability or factual findings that were established in those litigations; in one of the actions, the class was de-certified after a jury trial that resulted in a mistrial, and all of the other actions were resolved with the *Collins* settlement. *Collins* Pls.' Unopposed Mot. at 1, 3-5.

In addition, while Defendants' use of disclaimers may be relevant to the jury's consideration of challenged advertising and the net impression it conveys, Defendants can discuss their use of disclaimers without referring to the fact that disclaimers were required by the *Collins* settlement. There are no specific factual or legal findings pertaining to why or how the disclaimers from the *Collins* settlement exist; the fact that Defendants' use of the disclaimers resulted from the settlement is not a relevant matter for the jury's consideration and should be excluded.[7]

[7] To the extent that Defendants may wish to argue that their legal obligations under the *Collins* settlement pertaining to use of the disclaimers are relevant to the likelihood of future violations

B. The Court Should Exclude Any Reference by Defendants to the *Collins* Class Action, Including Revealing Its Existence or Any Specific Terms of the *Collins* Settlement, Because It Would Be Confusing and Potentially Misleading to the Jury, and Unfairly Prejudicial

Allowing Defendants to reference the existence of private litigation arising from similar facts to those in the instant case could confuse and mislead the jury, and be unfairly prejudicial. *See, e.g.*, *Arlio v. Lively*, 474 F.3d 46, 53 (2d Cir. 2007) ("[C]ourts are reluctant to cloud the issues in the case at trial by admitting evidence relating to previous litigation involving one or both of the same parties."); *Sharkey v. J.P. Morgan Chase & Co*., No. 10 Civ. 3824, 2017 WL 374735, at *4 (S.D.N.Y. Jan. 26, 2017) (excluding evidence of other lawsuits and settlements because "[a]ny probative value" would be "far outweighed by the risk of confusion and prejudice"). Jurors who learn that there has been private litigation that was resolved in 2020 may question why they are hearing a case brought by the NYAG years later, or whether such an action is duplicative, gratuitous, or unfair to Defendants. Further, any reference to the *Collins* settlement in particular has the potential to be highly prejudicial, as jurors may assume that Defendants have already paid for their deceptive acts. Even if the specific terms of monetary relief are not discussed, jurors could reasonably assume that a class action settlement may have provided monetary redress to purchasers. Such an assumption — in addition to being irrelevant to the issue of liability — would be incorrect. Restitution is available to New York consumers who purchased Prevagen from July 21, 2020 to the present — i.e., consumers who fall outside the *Collins* settlement class. *See People v. Applied Card Sys., Inc.*, 894 N.E.2d 1, 14 (N.Y. 2008)

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or the Court's determination of any injunctive relief that should be awarded following the liability phase, those arguments can be made solely before the Court after the liability phase of trial has concluded and have no relevance for the jury.

(class action settlement does not preclude the NYAG from seeking restitution for those not bound by the settlement).

Further, there are heightened risks of unfair prejudice because Defendants suggest the district court's approval of the *Collins* settlement somehow confers its endorsement or normative judgment of the disclaimers. S*ee* Defs.' Trial Br. (ECF 327-2) at 4. In fact, Defendants refer to the *Collins* disclaimers as "court-approved." *See id.* at 12. If Defendants were allowed to represent that they now use certain "court-approved" disclaimers as specified in the *Collins* settlement, jurors might incorrectly conclude that the *Collins* court determined that the disclaimers were effective and sufficient to remedy any deceptive statements in Defendants' advertising since the settlement.

The text of the Plaintiffs' Amended Unopposed Motion for Preliminary Approval of Class Action Settlement and Certification of the Settlement Class, and the Settlement Agreement and Release, provide no reason to believe that the judge in the *Collins* case conducted any analysis as to the effectiveness of the disclaimers described in the settlement agreement, or made any factual findings as to how the disclaimers might affect the net impression of any advertisements containing the claims at issue. *See generally Collins* Pls.' Unopposed Mot., Settlement Agreement and Release; *see also* Woo Decl. Ex. 5 (Minute Entry for Nov. 17, 2020 Proceedings, *Collins v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla. Nov. 17, 2020), ECF No. 198) (reflecting that the hearing held prior to approval of the class action settlement lasted for a total of 30 minutes). Certainly, the judge in *Collins* did not review any specific advertising Defendants generated after the settlement was finalized and that may be introduced by Plaintiffs at trial in the present matter.

Thus, not only do the existence of private litigation, the *Collins* action, and the *Collins* settlement hold no probative value for the jury, but any references to those topics should be excluded as confusing, misleading and unfairly prejudicial.

C. Any Reference by Defendants to the *Collins* Class Action Settlement Is Precluded by Rule 408

Federal Rule of Evidence 408 renders any evidence of the *Collins* settlement inadmissible if offered on the issue of Defendants' liability. For instance, under Rule 408, Plaintiffs would be precluded from introducing evidence of the *Collins* settlement during the trial to argue that Defendants' agreement to a settlement providing significant monetary and injunctive relief is an admission that the advertising challenged in that case was deceptive. Fed. R. Evid. 408 (prohibiting, *inter alia*, admission of evidence of a party's acceptance of an offer to compromise a claim "either to prove or disprove the validity or amount of a disputed claim"); *see also Playboy Enters. v. Chuckleberry Publ'g, Inc.*, 687 F.2d 563, 569 (2d Cir. 1982) (finding that Plaintiff's settlement agreement with another party in a prior trademark action was not admissible under Rule 408 as evidence probative of issues in instant Lanham Act case).

Likewise, Rule 408 prohibits a party from introducing evidence of its *own* settlement in other litigation for the purpose of disproving its own liability. *See* Fed. R. Evid. 408 (evidence of a settlement is "not admissible — on behalf of any party — either to prove or disprove the validity or amount of a disputed claim. . ."); *see also* Fed. R. Evid. adv. comm. notes – 2006 Amendment ("The amendment makes clear that Rule 408 excludes compromise evidence even when a party seeks to admit its own settlement offer or statements made in settlement negotiations."). The acceptance of the *Collins* settlement agreement terms by the covered

plaintiffs is not an admission or otherwise admissible evidence that the use of the disclaimers proscribed therein cures any deception in Defendants' advertising.[8]

Just as Rule 408 prevents Plaintiffs from arguing that the *Collins* settlement is evidence of Defendants' liability, it prevents Defendants from arguing that they are currently not engaged in deceptive advertising because they are using a disclaimer required by the settlement, as that is an argument that goes squarely to their liability. There is no admissible purpose for which Defendants can introduce evidence of the settlement pursuant to Rule 408 and for this reason any references to the settlement by Defendants must be excluded.

XIII. MOTION IN LIMINE 11: THE COURT SHOULD EXCLUDE ANY MENTION OF MONETARY RELIEF AT THE JURY TRIAL

Plaintiffs also seek to preclude Defendants from referencing the monetary relief being sought in this case. In its April 26, 2021 Opinion and Order (ECF No. 170) (at pp. 5-6), this Court concluded that Defendants had a right to a jury trial to determine their liability with respect to the NYAG's claims. The parties subsequently agreed that the determination of any monetary relief award should be made by the judge, following any jury verdict of liability on the NYAG's

[8] The terms of the *Collins* settlement itself specifically incorporate the broad protections of Rule 408:

> This Agreement is not to be construed or deemed as an admission of liability, culpability, negligence, or wrongdoing on the part of any of the Settling Defendants… The Settling Defendants deny all liability for claims asserted in the Action and the Prevagen Actions… This Agreement is a Settlement document and shall, pursuant to Fed. R. Evid. 408 and related or corresponding state evidence laws, be inadmissible in evidence in any proceeding. This Agreement or the existence of this Settlement shall not be used or cited in any proceeding other than (i) an action or proceeding to approve or enforce this Agreement, or (ii) in a subsequent proceeding potentially barred by the Release specified herein.

Settlement Agreement and Release at 16.

claims.[9] Thus, the only issue for the jury to decide is whether Defendants violated the New York statutes at issue in this case — not the relief to which the NYAG is entitled. The scope and nature of the monetary relief sought, including restitution, disgorgement of all profits obtained due to Defendants' fraudulent and illegal conduct, penalties, and costs, are irrelevant to the issues that the jury must decide.[10] It should therefore be excluded from any presentation to the jury, including attorney arguments. Alternatively, this information should be excluded as unduly prejudicial and a waste of the jury's time.

It is well established that finders of fact "must consider only the factual issue of liability without regard to any potential consequences which may befall a defendant." *SEC v. Moran*, No. 95 Civ. 4472, 1995 U.S. Dist. LEXIS 22807, at *3 (S.D.N.Y. Oct. 30, 1995); *see also Shannon v. United States*, 512 U.S. 573, 579 (1994) ("Information regarding the consequences of a verdict is . . . irrelevant to the jury's task."); *cf. United States v. Feuer*, 403 F. App'x 538, 540 (2d Cir. 2010) ("[A] defendant has no legal right to introduce evidence or argument regarding

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[9] *See* 9/13/23 Joint Letter to Hon. Louis L. Stanton (ECF No. 339) at 1-2 ("[S]hould liability be found, the Court would subsequently determine the appropriate remedies, including the equitable relief sought by both the FTC and the NYAG, as well as the amount of civil penalties to be awarded to the NYAG pursuant to New York General Business Law § 350-d.").

[10] New York Executive Law § 63(12) empowers the NYAG to bring an action for injunctive relief, restitution, and costs where any business has engaged in repeated or persistent fraudulent or illegal conduct. GBL § 349 similarly authorizes the NYAG to bring an action "to enjoin [deceptive] acts or practices and to obtain restitution of any moneys or property obtained directly or indirectly by any such unlawful acts or practices." GBL 350-d authorizes the Court to impose penalties of up to $5,000 for each violation of the GBL. Moreover, both Executive Law § 63(12) and GBL § 349 vest the Court with broad equitable powers to redress fraudulent and illegal conduct. Thus, New York courts have held that disgorgement of profits is an appropriate equitable remedy under Executive Law § 63(12). *People v. Greenberg*, 54 N.E.3d 74, 77 (N.Y. 2016). Remedial orders pursuant to these statutes are "addressed to the sound discretion of the court." *State v. Princess Prestige Co.*, 366 N.E.2d 61, 63 (N.Y. 1977) (N.Y. Exec. Law § 63(12)); *see also People v. Gen. Elec.*, 756 N.Y.S.2d at 523; *State v. Maiorano*, 592 N.Y.S.2d 409, 409 (App. Div. 1993).

sentencing consequences."); *United States v. Del Rosario*, No. S1 12 Cr. 81, 2012 U.S. Dist. LEXIS 86291, at *4 (S.D.N.Y. June 14, 2012) ("There is no basis upon which defendant would be allowed to introduce into evidence, or even refer, to any possible punishment that may follow a conviction on the count charged."). Here, any discussion of the monetary relief sought by the NYAG should be excluded because the relief sought constitutes the consequence of the jury's verdict — not the basis for the verdict. *See Moran*, 1995 U.S. Dist. LEXIS 22807, at *3; *see also SEC v. Spencer Pharm., Inc.*, 58 F. Supp. 3d 165, 166 (D. Mass. 2014) ("None of the statutory provisions under which [defendant] is charged include an element related to either the effects of the investigation or the possible consequences of trial. Accordingly, such evidence is irrelevant to a determination of [defendant's] liability for the charges brought against him.") (citations omitted).

Here, the NYAG's first count is under New York Executive Law § 63(12), which prohibits repeated and persistent fraudulent and illegal conduct. Compl. (ECF No. 1) ¶¶ 42-43. The NYAG's second count alleges violations of GBL §§ 349 and 350. GBL § 349 prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. Gen. Bus. Law § 349. GBL § 350 prohibits "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. Gen. Bus. Law § 350. None of the elements for finding a violation of the New York statutes at issue in this case — the sole role of the jury here — hinges on the monetary relief the NYAG will seek from the judge if a violation is found. Any reference before the jury of the monetary relief sought in this case should therefore be excluded under Rules 401 and 402.

Evidence of the monetary relief sought should also be excluded under Rule 403 because it would cause prejudice, confusion, and a waste of time. Such evidence would invite the jury to

consider matters outside their assigned task of determining liability only and could "distract[] them from their factfinding responsibilities, and create[] a strong possibility of confusion." *Shannon*, 512 U.S. at 579; *see also Torcivia v. Suffolk Cty.*, 17 F.4th 342, 366 (2d Cir. 2021) (holding district court did not abuse its discretion in excluding evidence under FRE 403 that district court believed "would add more to the confusion of the case than it will clarify matters"). Such information could also prejudice the jury by inviting them to make their liability determination based on factors unrelated to the factual issues before them. *See United States v. Paccione*, 949 F.2d 1183, 1201 (2d Cir. 1991) (holding district court acted well within its discretion in excluding evidence that fraud defendant's son had cerebral palsy because such evidence "could well cause the jury to be influenced by sympathies having no bearing on the merits of the case"). If the jury hears mention of the monetary relief sought in this case, they may be persuaded to base their liability determinations not on whether the NYAG has successfully proven the required elements of its claims, but rather based on their opinion about whether the NYAG is entitled to the full scope of the monetary relief it is seeking. *See* Fed. R. Evid. 403, adv. comm. notes (courts will exclude evidence if it has "an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one"); *see also United States v. Aiyer*, 33 F.4th 97, 126 (2d Cir. 2022) (district court properly excluded evidence unrelated to elements the government had to prove because admitting it risked "cloud[ing] the issue" and that "would have potentially confused or misled the jury") (citation omitted). The danger of prejudice is all the more significant in this case, in which Defendants have made much of the purportedly "exorbitant" and "outsized" monetary relief the NYAG is seeking. Defs.' Br. in Reply to Pls.' Opp. to a Jury Trial (ECF No. 162) at 11. While the NYAG disagrees with Defendants' characterization of the relief the NYAG seeks, such issues — and the

dramatic language Defendants use to discuss them — should remain outside the jury's purview. *See, e.g.*, *id.* at 11 ("By the NYAG's own calculations, the NYAG alone is seeking some unknown multiple of $50 million civil penalties (based on its purported claim it can receive $5,000 for *each day* Prevagen has been sold and *each day* Prevagen was available via website)." (emphases in original); *id.* at 10 (in arguing that the "primary relief" the NYAG seeks is monetary, noting that "the NYAG intends to calculate restitution and disgorgement in the full amount of Quincy's net profits from the sale of Prevagen in New York from 2007 through the present"); *id.* at 11 (arguing that "the civil penalties being sought are so expansive they are almost incalculable").

Given the irrelevance of this evidence, and the substantial risks of unfair prejudice, confusing the issues, and wasting time, any evidence or argument regarding the monetary relief sought by Plaintiffs should be excluded under Rules 401, 402, and 403.

XIV. CONCLUSION

For the foregoing reasons, Plaintiffs request that the Court exclude arguments and evidence relating to: whether Plaintiffs have proffered extrinsic evidence about consumers, advertising, or marketing (Motion in Limine 1); whether Plaintiffs have conducted scientific research or human clinical trials (Motion in Limine 2); Dr. Kurzer's opinions on Vitamin D (Motion in Limine 3); FTC Guidance (Motion in Limine 4); Defendants' experts' opinions on the amount and type of evidence needed to substantiate the challenged claims (Motion in Limine 5); good faith (Motion in Limine 6); advice of counsel (Motion in Limine 7); research or advertising practices of other companies (Motion in Limine 8); FDA approval of Aduhelm (Motion in Limine 9); the existence of private litigation involving Prevagen, including the *Collins* class action (Motion in Limine 10); and monetary relief (Motion in Limine 11).

Respectfully submitted,

Dated: October 24, 2023

FEDERAL TRADE COMMISSION

By: /s/ *Andrew Wone*

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of October, 2023, I have caused service of the foregoing Plaintiffs' Memorandum in Support of Their Motions in Limine to be made by electronic filing with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record.

Dated: October 24, 2023

/s/ Andrew Wone
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Federal Trade Commission